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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/568,324	10/13/2006	Bob Coyne	14923.0035	4626
27890	7590	03/28/2008	EXAMINER	
STEPTOE & JOHNSON LLP 1330 CONNECTICUT AVENUE, N.W. WASHINGTON, DC 20036				CHEN, CATHERYNE
ART UNIT		PAPER NUMBER		
		1655		
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		03/28/2008		PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/568,324	COYNE ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	CATHERYNE CHEN	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 03 January 2008.  
 2a) This action is **FINAL**.                  2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-51 and 59-63 is/are pending in the application.  
 4a) Of the above claim(s) 37-38 is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 1-36,39-51 and 59-63 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on 03 January 2008 is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____ .
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>Feb. 20, 2008</u> .	5) <input type="checkbox"/> Notice of Informal Patent Application
	6) <input type="checkbox"/> Other: _____ .

## **DETAILED ACTION**

The Amendments filed on Jan. 3, 2008 has been received and entered.

Currently, Claims 1-51, 59-63 are pending. Claims 1-36, 39-51, 59-63 are examined on the merits. Claims 52-58, 64-67 are canceled.

### ***Election/Restrictions***

Applicant's election without traverse of Group I (Claims 1-51, 59-64, 66-67), the species Lactococcus-derived bacteriocin, rosemary, phenolic diterpene being carbosic acid, phenolic triterpene being ursolic acid, raw meat, citric acid esters of monodiglycerides, polyphosphates in the reply filed on June 22, 2007 is acknowledged.

Claims 37, 38 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected group and species, there being no allowable generic or linking claim. The organisms in Claims 37 and 38 are not included with the species selected; thus, they are deemed not elected.

### ***Response to Arguments***

#### ***Claim Rejections - 35 USC § 101***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

In the previous Office action, Claims 59-62 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153

USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

***Claim Rejections - 35 USC § 112***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

In the previous Office action, Claims 1, 59-62 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 59-62 provide for the use of an antimicrobial material and extract obtained from Labiateae family. The claims are indefinite because it is not clear if applicant is claiming a method or a composition. For the sake of examination, these claims will be considered as composition claims. Applicant must indicate whether the claim is a composition or a process. The "use" language is not an accepted category of invention in U.S. practice.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely

exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 1 recites the broad recitation “an antimicrobial material,” and the claim also recites “consists of nicin” which is the narrower statement of the range/limitation.

***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-11, 13-20, 22-36, 47-51, 59, 61-63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sonnenberg et al. (US 2002/0173436 A1) for the reasons set forth in the previous Office Action. All of Applicant's arguments regarding this ground of rejection have been fully considered but are not persuasive. Applicant argues that there is no motivation to use the reference to make the composition at the claimed concentrations.

Sonnenberg et al. teaches soap with antimicrobials (paragraph 0050), rosemary oil, thyme oil (paragraph 0055), carvone (paragraph 0062), thymole, carcacrol (paragraph 0079), rosemary, thyme (paragraph 0091), nisin, bacteriocins, lysozyme (paragraph 0115), chelating agents (paragraph 0138). The reference does teach that each of the claimed ingredients is suitable for combination in an antimicrobial composition. Thus, an artisan of ordinary skill would be reasonably expected that the claimed ingredient could be combined together to produce a single antimicrobial

product. This reasonable expectation of success would motivate the artisan to combine the claimed ingredients together into a single composition. While the reference might not teach a specific embodiment with the claimed ingredients, the reference does list these ingredients as being appropriate for combination into a dietary food used for performing health. As discussed in KSR International Co. v. Teleflex Inc., 550 U.S.--, 82 USPQ2d 1385 (2007) it is considered obvious to combine prior art elements known to be used in equivalent fields of endeavor together into a single combination. The reference clearly shows that the claimed ingredients were known to be used in equivalent fields of endeavor; thus, it is considered obvious to combine them together.

The amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Thus, optimization of general conditions is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of applicant's invention.

Claims 1-36, 39-51, 59-63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Todd, Jr. (US 5084293), Bard et al. (US 3679434), and King et al.

(US 6451365 B1) for the reasons set forth in the previous Office Action. All of Applicant's arguments regarding this ground of rejection have been fully considered but are not persuasive. Applicant argues that there is no motivation to combine references, concentrations are not taught.

Todd, Jr. teaches antioxidant use for meats (column 1, lines 56-60), rosemary in food stuff (column 5, lines 55-58), emulsifier of citric acid esters of mono-diglycerides (column 18, line 18). However it does not teach nisin, the specific concentrations, and raw meat.

Bard et al. teaches fresh (uncured) meat with edible polyphosphate salts to prevent the development of rancidity (column 2, lines 65-69).

King et al. teaches antibacterial composition against gram positive bacteristatic of lytic enzymes, bacteriocins apply to solid food (Abstract), use of nisin as bactericides against bacterium Lactoccus lactis and against gram negative bacteria (column 2, lines 43-59), lysozyme, polyphosphates, EDTA (column 3, lines 27-32).

Rosemary is considered to intrinsically teach the claimed phenolic diterpenes, triterpenes, ursolic acid and rosmarinic acid because both the reference and the claimed invention are using the same composition.

Meat can be spoiled by bacteria and undergoes oxidation. Thus, an artisan of ordinary skill would reasonably expect that anti-oxidants, antimicrobicides, agents to prevent rancidity could be used as the types of composition taught by the references. This reasonable expectation of success would motivate the artisan to use all of the

claimed ingredients in the reference composition. Thus, using all of the claimed ingredient is considered an obvious modification of the references.

The references also do not specifically teach adding the ingredients in the amounts claimed by applicant. The amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Thus, optimization of general conditions is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of applicant's invention.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CATHERYNE CHEN whose telephone number is (571)272-9947. The examiner can normally be reached on Monday to Friday, 9-5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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